

REMARKS

Claims 21-24 and 28-36 are pending. Claim 21 has been amended. The amendments to claim 21 are supported, for example, by previous versions of claim 21 and by the specification, for example, at page 4, lines 4-6. No new matter has been introduced by these amendments. Applicant respectfully request reconsideration of the rejection based on the following comments.

Applicant thanks Examiner for granting the telephonic interview on June 12, 2009 with Applicant's undersigned representative and Peter S. Dardi, Ph.D. In the interview, language to overcome the rejection was discussed. Examiner indicated the possibility that replacing "to drive apart the surfaces" with "and thereby driving apart the surfaces" or "resulting in the driving apart of the surfaces" in claim 21 might overcome the rejections after further consideration and search. If the Examiner still has concerns regarding the positive recitation of the surface separation language, the Examiner is respectfully asked to call Applicant's undersigned representative.

***Rejection under 35 U.S.C. § 112***

Claims 21-24 and 28-36 were rejected under 35 USC 112, first and second paragraphs. In the Advisory Action dated April 14, 2009, Examiner indicated that Applicant's response dated March 30, 2009 has overcome the rejections under 35 USC 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs. Below, we present the portion of the response dated March 30, 2009 that addresses these 112 rejections.

Claims 21-24 and 28-36 were rejected under 35 USC 112, first paragraph, for alleged for failure to comply with the written description requirement. To advance prosecution, Applicant has amended claim 21 to delete some potentially confusing language. Unfortunately, the Examiner did not state what specific language was not supported by the written description. As stated in the MPEP 2163 III, the "Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections." As stated in MPEP 2163 III.A.(emphasis

added): "The examiner, therefore, **must** have a reasonable basis to challenge the adequacy of the written description. The examiner has the **initial burden** of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. ... In rejecting a claim, the examiner **must** set forth express findings of fact regarding the above analysis which support the lack of written description conclusion." With all due respect, the Examiner simply has not done this. Even though the Examiner has completely failed to establish *prima facie* lack of written description, Applicant will nevertheless present arguments to advance prosecution on this issue in an attempt to limit further delays in prosecution.

The feature "A method for immobilizing a patient's sacroiliac joint through a passageway provided by an extra-articular recess into the sacroiliac joint wherein the sacroiliac joint and the extra-articular recess are formed by a surface of an ilium bone and a surface of a sacrum bone" is clearly supported. Original and current versions of figure 3 show the immobilization element inserted in between the surfaces of the sacroiliac joint and the extra-articular recess. A person of ordinary skill in the art would be an orthopedic surgeon or an experienced medical engineer. It is inconceivable that a person of ordinary skill in the art would not understand possession of the presently claimed invention based on the specification at filing.

Furthermore, with reference to the specific claim language, the feature "...inserting an immobilization/fusion element into the sacroiliac joint between the ilium and the sacrum bones through the extra-articular recess to drive apart the surface of the ilium and sacrum bones that form the sacroiliac joint and adjoining surfaces of the extra-articular recess..." is also clearly supported, for example, by the specification at page 4, lines 4-6 ("presumably immobilization of the joint reduces or eliminates contact between worn or damaged sections of the joint") and at page 5, line 16 ("the immobilization element can be...a wedge"). These quotations clearly support the present claim language since they make absolutely no sense in any context other than

in the circumstance of the present claim language. Original and current versions of figure 3 show an immobilization element inserted in between the surfaces of the sacroiliac joint and the extra-articular recess in such a way as to drive apart the surfaces of the ilium and sacrum bones. See, also for example, the cross over paragraph between pages 1 and 2. As the specification on page 4, lines 4-6 discloses, the immobilization element drives apart the surfaces of the ilium and sacrum bones by reducing or eliminating contact between them. The immobilization element can be a wedge that wedges between or drives apart the ilium and sacrum bone surfaces. Figure 3 and the written specification throughout clearly support the insertion of an immobilization element into the sacroiliac joint along an opening into the joint in a manner that drives apart the surfaces of the ilium and sacrum bones.

The feature “wherein the element is inserted through a cannula, over a pin, or both” is supported, for example, by the specification at page 4, lines 19-23 (“In particular, a small incision can be made into which an orienting probe or pin is inserted. The placement of the cannula can be guided by the probe, and once the cannula is in place, the probe/pin can be removed, cut down or used to guide the placement of an immobilization element, such as a cannulated screw placed over the pin.”) The specification clearly supports inserting the immobilization element through a cannula, over a pin, or both.

Clearly, the specification provides clear written description for the present claim language. A person of ordinary skill in the art would not question whatsoever the possession of the presently claimed invention. *Prima facie* lack of written description has not been established, and Applicants have clearly provided a clear and well supported basis for written description. Based on the comments above, Applicants respectfully request withdrawal of the rejection.

Claims 21-24 and 28-36 were rejected under 35 USC 112, second paragraph, for alleged lack of clarity for “ligmentotaxis” in claim 21. Since this feature has been removed from the claim, Applicants respectfully request withdrawal of the rejection.

***Rejection under 35 U.S.C. § 102(b) by Cain***

The Examiner rejected claims 21-23, 28, 29, 32, 33, 35 and 36 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,334,205 to Cain (Cain). Claim 21 has been amended to more particularly point out Applicants' invention. Applicants respectfully request withdrawal of the rejection.

Cain fails to disclose the features of claim 21. For example, claim 21 recites "...the method comprising *inserting an immobilization/fusion element into the sacroiliac joint between the ilium and the sacrum bones through the extra-articular recess and thereby driving apart the surfaces of the ilium and sacrum bones that form the sacroiliac joint and adjoining surfaces of the extra-articular recess.*" To fix loosened sacroiliac joints, Cain discloses tightening or securing the joint by using fixation screws to drive the surfaces of the ilium and sacrum bones closer together. Applicant's invention is directed to inserting an element into the sacroiliac joint and thereby driving apart the surfaces of the ilium and sacrum bones while Cain's invention is directed to inserting an element across the sacroiliac joint and thereby driving together the surfaces of the ilium and sacrum bones. Any modification of Cain to provide for the features of Applicants' claimed invention would render Cain unsatisfactory for its intended purpose and radically change the principle of operation of Cain.

Cain clearly fails to *prima facie* anticipate or render obvious claim 21. Accordingly, claim 21 and its dependent claims 22-24 and 28-36 should be allowed. While Applicants do not acquiesce with respect to the specific assertions regarding the features of the dependent claims, these issues are presently moot in light of the discussion above.

***Rejection under 35 U.S.C. § 103(a) over Cain in view of Chang et al.***

The Examiner rejected claim 24 under 35 U.S.C. § 103(a) as being unpatentable over Cain in view of U.S. Patent Publication 2002/0099288 to Chang et al. (Chang). As discussed above, Cain fails to disclose or suggest the limitations of claim 21 as amended. Chang fails to remedy the deficiencies of Cain. Specifically, Chang fails to disclose or suggest “...the method comprising *inserting an immobilization/fusion element into the sacroiliac joint between the ilium and the sacrum bones through the extra-articular recess and thereby driving apart the surfaces of the ilium and sacrum bones that form the sacroiliac joint and adjoining surfaces of the extra-articular recess.*” Thus, the combined teachings of these references do not teach this feature of the presently claimed invention. The references alone or combined do not render Applicant's claimed invention *prima facie* obvious. Applicant does not acquiesce with respect to the specific assertions regarding the features of these claims, but these issues are rendered moot in light of the discussion above.

***Rejection under 35 U.S.C. § 103(a) over Cain in view of Bowman et al.***

The Examiner rejected claims 30 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Cain in view of U.S. Patent 4,950,270 to Bowman et al. (Bowman). As discussed above, Cain fails to disclose or suggest the limitations of claim 21 as amended. Bowman fails to remedy the deficiencies of Cain. Specifically, Bowman fails to disclose or suggest “...the method comprising *inserting an immobilization/fusion element into the sacroiliac joint between the ilium and the sacrum bones through the extra-articular recess and thereby driving apart the surfaces of the ilium and sacrum bones that form the sacroiliac joint and adjoining surfaces of the extra-articular recess.*” Thus, the combined teachings of these references do not teach this feature of the presently claimed invention. The references alone or combined do not render Applicant's claimed invention *prima facie* obvious. Applicant does not acquiesce with respect to

the specific assertions regarding the features of these claims, but these issues are rendered moot in light of the discussion above.

***Rejection under 35 U.S.C. § 103(a) over Cain in view of Helland***

The Examiner rejected claim 34 under U.S.C. § 103(a) as being unpatentable over Cain in view of U.S. Patent 4,488,542 to Helland. As discussed above, Cain fails to disclose or suggest the limitations of claim 21 as amended. Helland fails to remedy the deficiencies of Cain. Specifically, Helland fails to disclose or suggest “...the method comprising *inserting an immobilization/fusion element into the sacroiliac joint between the ilium and the sacrum bones through the extra-articular recess and thereby driving apart the surfaces of the ilium and sacrum bones that form the sacroiliac joint and adjoining surfaces of the extra-articular recess.*” Thus, the combined teachings of these references do not teach this feature of the presently claimed invention. The references alone or combined do not render Applicant's claimed invention *prima facie* obvious. Applicant does not acquiesce with respect to the specific assertions regarding the features of these claims, but these issues are rendered moot in light of the discussion above.

***Rejection under 35 U.S.C. § 103(a) over Cain in view of Skiba***

The Examiner rejected claim 34 under U.S.C. § 103(a) as being unpatentable over Cain in view of US Patent 5,743,914 to Skiba. As discussed above, Cain fails to disclose or suggest the limitations of claim 21 as amended. Skiba fails to remedy the deficiencies of Cain. Specifically, Skiba fails to disclose or suggest “...the method comprising *inserting an immobilization/fusion element into the sacroiliac joint between the ilium and the sacrum bones through the extra-articular recess and thereby driving apart the surfaces of the ilium and sacrum bones that form the sacroiliac joint and adjoining surfaces of the extra-articular recess.*”

Thus, the combined teachings of these references do not teach this feature of the presently claimed invention. The references alone or combined do not render Applicant's claimed invention *prima facie* obvious. Applicant does not acquiesce with respect to the specific assertions regarding the features of these claims, but these issues are rendered moot in light of the discussion above.

CONCLUSIONS

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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